DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

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DEPUTY UNDER SECRETARY FOR HEALTH FOR OPERATIONS AND MANAGEMENT'S INFORMATION LETTER

IMEDCONSENT™ GUIDANCE

1. This Veterans Health Administration (VHA) Information Letter clarifies expectations for use of the iMedConsent™ software program and establishes guidelines for local customization of the consent forms in the iMedConsent™ library. Informed consent for treatments and procedures is essential to high quality patient care. Implementation of national standards for the informed consent process will help ensure that veterans across the country receive the information that they need before giving their consent to treatment.

2. Once implemented in a specialty, iMedConsent™ should be used to electronically generate, sign, and store consent forms for clinical treatments and procedures. If iMedConsent™ is unavailable due to a system failure, or if the patient is uncomfortable using the signature pad, consent may be obtained using a paper form (physicians should print the form in iMedConsent™ if possible).

3. At this time, paper forms should also be used to document consent in emergency situations, consent over the telephone, consent for employee health, and consent for research. The iMedConsent™ program may be modified to accommodate these processes in the future.

4. Clinicians will continue to be able to modify consent forms on a case-by-case basis to reflect each patient's medical condition. However, clinicians should use their discretion appropriately. Risks, benefits, and alternatives disclosed on consent forms must be consistent with informed consent policy (see Handbook 1004.1, Informed Consent for Clinical Treatments and Procedures). It is not appropriate, for example, to delete this information and write "as discussed." Nor is it appropriate to add boilerplate risks that are not known to be associated with a particular procedure.

5. Facilities should not modify nationally standardized consent forms in iMedConsent™. Report problems and concerns related to nationally approved consent form content to Dialog Medical (enterprise@dialogmedical.com).

6. Facilities should not create local versions of national consent forms in iMedConsent™. Administrators of iMedConsent™ who have created local versions of national content should delete these forms immediately and instruct clinicians to use the nationally-approved forms.

7. Facilities should add consent forms to their local library for treatments and procedures that are not included in the iMedConsent™ library. However, copies of locally created clinical consent forms should be sent to the vendor, Dialog Medical, for evaluation (enterprise@dialogmedical.com). If the form duplicates a form in the national library or is otherwise inappropriate, a facility may be instructed to delete the form from its library. Once a national version of a consent form is released, facilities should delete the corresponding locally created consent form and instruct clinicians to use the national form.

8. Facilities should complete an informed consent workflow analysis for every specialty in which iMedConsent™ is (or will be) deployed as was directed at implementation (for details on performing this analysis, see http://vaww.patientdecisions.va.gov/PATIENTDECISIONS/docs/workflow.pdf).

9. iMedConsent™ was recently modified to allow facilities to add local treatment and procedure-specific information to the national consent form. Locally added content should not contain risk, benefit, or alternative information, and should be reviewed by the relevant specialty chief at each facility.

10. In a memo dated May 31, 2005, the Deputy Under Secretary for Health Operations and Management issued a limited moratorium on the purchase of new hardware such as Tablet Personal Computers (PCs) for use with iMedConsent™ pending the results of an assessment. The moratorium is lifted with this information letter.

11. A variety of mobile solutions are in use throughout VHA for wireless and/or mobile implementation of iMedConsent. Each facility possesses unique characteristics which make a "single solution" impractical. Facilities should perform user-based evaluations of the cart or Tablet PC they believe will best meet their needs before purchasing multiple units. The evaluation should include simulated "consenting" scenarios in the desired deployment locations. End user participation in these evaluations is necessary to ensure that the equipment is manageable in informed consent workflows. The Bar Code Medication Administration (BCMA) Program Management Office has created guidance for evaluating mobile carts for use with BCMA. This same method would be appropriate for use with iMedConsent and can be found at http://vaww.va.gov/bcmapmo/page.cfm?pg=13.

12. Except in the simplest of cases, VA staff should not service mobile carts unless they have received proper training and instruction from the vendor of the devices.

13. If there is concern whether the mobile device being considered for purchase is compatible with the iMedConsent software, Dialog Medical may be contacted at enterprise@dialogmedical.com.

14. The National Center for Ethics in Health Care is coordinating the iMedConsent™ rollout. The Office of Patient Care Services is responsible for the content in the iMedConsent™ clinical library. For more information, visit the initiative website: http://vaww.patientdecisions.va.gov.

S/William F. Feeley, MSW, FACHE
Deputy Under Secretary for Health for
Operations and Management

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